

## **REMARKS**

The Office Action of July 8, 2005 has been received and reviewed. Claims 1-6, 8-48, and 50 are cancelled herein without prejudice or disclaimer. Claims 7 and 49 are amended herein without prejudice or disclaimer. Pending claims 7 and 49 are herein presented. Applicants respectfully request reconsideration. Support for amended claim 7 can be found in at least paragraph [0013] of the published US application; US 2004/0092446 A1 (hereinafter referred to as US'446). Support for amended claim 49 can be found in at least paragraph [0021] of US'446. No new matter has been added.

### **Objections to Specification**

The disclosure stands objected to as allegedly containing informalities. While not agreeing with the Examiner, but to further prosecution of the case, Applicants have made amendments commensurate with the Examiner's suggestions. All such amendments are made without prejudice or disclaimer.

Applicants have amended the brief description of Figures 5, 6, 7 and 8 to contain the symbols present in US 6,878,375, a parent case. Accordingly, Applicants request reconsideration and withdrawal of the objection.

Applicants have cancelled reference to the colors of red and green in the Brief Description of Figure 12. Accordingly, Applicants request reconsideration and withdrawal of the objection.

Applicants have amended line 2, of page 37, of the originally submitted specification, now paragraph [0108], to change "b" to "β". Accordingly, Applicants request reconsideration and withdrawal of the objection.

Applicants have removed the hyperlink on page 53, line 20 of the originally submitted specification, now paragraph [0156]. Accordingly, Applicants request reconsideration and withdrawal of the objection.

The Examiner contends that Tables 3-6 include sequence information that is not identified by a SEQ ID number. Applicants have made appropriate amendments. For Table 3, Applicants have added the Sequence ID numbers to paragraph [0156] in reference to the disclosed peptides, thereby identifying the sequence information. For Tables 4 and 5, Applicants

have amended paragraph [0172] to make appropriate reference to the sequences corresponding to the disclosed fragments, thereby identifying the sequence information. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection.

Applicants have cancelled references to bold amino acid residues in the legend to Tables 4 and 5. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection.

### **Claim Objections**

Claims 7 and 49 stand objected to as depending from withdrawn claims. Applicants have amended claim 7 and 49 to overcome the objection and cancelled claims 1-6, 8-48, and 50. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection.

### **Rejections under 35 USC §112, 1<sup>st</sup> ¶**

Claims 7, 12-19, 30, 31, 35, 36, 45 and 46 stand objected to as allegedly failing to comply with the written description and enablement requirements. In light of the amendments to claims 7 and 49 and the following analysis, Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner alleges that the specification does not disclose how an administered HA-1 peptide induces both tolerance and CTL generation. In light of the cancellation of dependent claims 12-19, 30, 31, 35, 36, 45, and 46, Applicants respectfully request reconsideration and withdrawal of the rejection, as it is now believed to be moot.

Claim 7 is further rejected for allegedly not providing written description of how HA-1 is involved in any autoimmune disease. While not agreeing with the Examiner, Applicants have amended claim 7 to remove the element of an autoimmune disease. Applicants respectfully request reconsideration and withdrawal of the rejection, as it is now believed to be moot.

Claim 7 is further rejected for allegedly not providing written description of how the administration of HA-1 prevents transplant rejection and/or GvHD. While not agreeing with the Examiner, claim 7 has been amended in order to recite that transplant rejection and/or GvHD is prevented or mitigated. Basis can be found in paragraph [0013] of US'446. Accordingly, Applicants respectfully assert that this rejection is now moot. Therefore, Applicants respectfully

request reconsideration and withdrawal of the rejection.

Claim 7 stands further rejected as allegedly not reciting that the patient being administered an HA- 1 peptide has received or will be receiving a tissue or organ graft that is HLA-matched. Applicants have amended claim 7 such that amended claim 7 now requires the patient to receive an HLA-matched graft. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection, as the rejection is now believed to be moot.

Claim 7 stands further rejected as allegedly not disclosing an HA-1 peptide capable of binding to a MHC class I or II molecule. However, the Examiner admits that Applicants have disclosed amino acid polymorphism located within peptide sequence consisting of SEQ ID NO:1, with the two possible sequences disclosed, one as SEQ ID NO:2 which has an H at position 3 (HA allele, VLHDDLLEA), and, two as SEQ ID NO:10 which has an R at position 3 (HA allele, VLRDDLLEA). Further, US'446 discloses, in paragraph [0011], that a peptide provided by the invention contains necessary anchoring residues for presentation in a groove of an HLA-A2.1 molecule, which is a MHC class I molecule. Reconsideration and withdrawal of the rejection is therefore requested.

Claim 7 stands further rejected as allegedly not requiring a patient to express HLA-A2.1 or-B60. Amended claim 7 now has as an element that the subject is HLA-A2.1 positive. Accordingly, the rejection is believed overcome and Applicants request reconsideration and withdrawal of the rejection.

Claim 7 stands further rejected as allegedly not providing guidance or working examples for HA-1 derivatives. Applicants have removed the element of derivatives and analogs, thereby mooting the rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim 7 stands further rejected as allegedly not providing written description of how administration of a peptide comprising HA-1<sup>R</sup> (SEQ ID NO: 10) to an individual will be therapeutically useful. Applicants respectfully request withdrawal of the rejection and reconsideration in light of the amendments to claim 7, wherein claim 7 does not refer to HA-1<sup>R</sup> (SEQ ID NO: 10). Accordingly, the rejection is avoided.

Claim 7 stands further rejected as allegedly not reciting that the way in which a peptide is administered can make a stimulatory peptide into a toleragenic peptide. Applicants have

amended claim 7 to include the element of a "tolerance-inducing dose". Accordingly, the rejection is moot and Applicants respectfully request reconsideration and withdrawal of the rejection.

### CONCLUSION

The rejections are believed to be overcome, and the application is believed to be in a condition for allowance. If, however, questions remain after consideration of the foregoing, the Office is kindly requested to contact Applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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